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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HUNT, JENNIFER ELIZABETH

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/02/2002 30

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/164,862

Applicant(s)

Price et al.

Examiner

Jennifer Hunt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 2, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 38, 39, 47, 49-52, and 54-62 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 38, 39, 47, 49-52, and 54-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Response to Amendment

1. Acknowledgment is made of applicant's cancellation of claims 48 and 53. Claims 1-18, 38-39, and 47, 49-52, and 54-62 are pending in the application and currently under consideration.

Claim Objection/Rejections Withdrawn

2. All rejections of claims 48 and 43 are withdrawn in light of the cancellation thereof.

3. The objections to claims 38 and 51 as improper because they appear to contain a typographical error is withdrawn in light of the amendments thereto.

4. The rejection of claims 1-8 and 47-62 under 35 U.S.C. 112 second paragraph as improper because it cannot be determined what sample is being tested, what sample is the control, and from which sample/correlations the various correlations are determined is withdrawn in light of the amendments thereto.

5. The rejection of claims 1-18 under 35 U.S.C. 112 second paragraph as incomplete because they omit essential steps is withdrawn in light of the amendments thereto.

6. The rejection of claim 10 as improper because it contains an improper Markush Group is withdrawn in light of the amendments thereto.

7. The rejection of claim 11 under 35 U.S.C. 112 second paragraph as unclear in the recitation of "level" and "immunohistochemical staining" is withdrawn in light of applicant's arguments.

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8. The rejection of claim 39 under 35 U.S.C. 112 second paragraph as unclear in the recitation of a “multiplicity of instances” is withdrawn in light of applicant’s arguments and clarification of the record.
9. The rejection of claim 47 under 35 U.S.C. 112 second paragraph for the vague and indefinite recitation of a “statistically significant difference” is withdrawn in light of applicant’s arguments and clarification of the record.
10. The rejection of claim 49 under 35 U.S.C. 112 second paragraph as unclear in the recitation of “whole blood” is withdrawn in light of applicant’s arguments and clarification of the record.
11. The rejection of pending claims 1, 9-13, 15-17, 38, 39, 47, 49-50, 56-57, and 59-61 under 35 U.S.C. 102(b) as being anticipated by Johansen et al., European Journal of Cancer, Vol. 31A, No. 9, pp1437-1442, 1995 is withdrawn in light of applicant’s amendments thereto.
12. The rejection of pending claims 47, 49, and 56-62 under 35 U.S.C. 102(e) as being anticipated by Robbins et al., US Patent 5,726,061, filed 10/8/1996, issued 3/10/98 is withdrawn in light of applicant’s amendments thereto.

Claim Rejections Maintained/New Grounds of Rejection

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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14. The rejection of claim 49 under 35 U.S.C. 112 second paragraph as improper because it contains an improper Markush Group is maintained for reasons of record, as applicant has neither argued the rejection, nor amended the claim. The appropriate Markush format is "selected from the group consisting of....and". Deletion of "or" and substitution therefor of --and-- would obviate this rejection.

15. The rejection of claim 11 under 35 U.S.C. 112 second paragraph as unclear in that it cannot be determined how cells comprise a biological sample is maintained for reasons of record.

Applicant argues by citing the Cambridge International Dictionary of English definition of the verb comprise, which reads: "to have as parts or members, or to be (those parts or members)". Thus applicant argues that comprise can be used to refer to the whole, or the parts/members of the whole. Applicant's arguments filed 10-02-2001 have been fully considered but they are not persuasive.

In traditional English and patent usage of the term, the whole *comprises* the parts, while the parts *compose* the whole. See MPEP 2111.03, which makes it clear that in patents, the term comprising is meant to modify a whole which comprises parts or members:

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

Further, specifically addressing the Cambridge International Dictionary of English definition as cited by applicant is applied, the usage is not correct. The example cited in the Cambridge International Dictionary of English for instances where comprise modifies the "parts or members" states "Italian students comprise 60% of the class". Thus as set forth previously,

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the recitation is proper if it recites that the cells are comprised within (or as a part of) a biological sample, or a biological sample comprising cells which are...

16. The rejection of claim 38 under 35 U.S.C. 112 second paragraph as unclear in the recitation of a "possible recurrence" of cancer is maintained for reasons of record.

Applicant argues that one of skill in the art would readily understand the metes and bounds of a "possible recurrence". Applicant's arguments filed 10-02-2001 have been fully considered but they are not persuasive.

As set forth in the previous action, it is not clear what would be considered a "possible recurrence" and what would not. It is not clear what standards or measures could be used to determine a "possible recurrence". The term "possible" is a relative term which renders the claim indefinite. The term "possible" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Specifically, how likely must an occurrence be to be "possible" as intended by the instant claim?

17. Claim 52 recites the limitation "breast cancer". There is insufficient antecedent basis for this limitation in the claim.

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

19. The rejection of claim 52, under 35 U.S.C. 102(b) as being anticipated by Johansen et al., European Journal of Cancer, Vol. 31A, No. 9, pp1437-1442, 1995 is maintained for reasons of record.

Applicant argues that the claim no longer encompasses breast cancer. Applicant's arguments filed 10-02-2001 have been fully considered but they are not persuasive.

The claim is drawn specifically to detection of breast cancer, and thus the reference anticipates the claim.

20. The rejection of pending claims 1 and 4-18 under 35 U.S.C. 102(e) as being anticipated by Robbins et al., US Patent 5,726,061, filed 10/8/1996, issued 3/10/98 is maintained for reasons of record.

With regard to claims 1 and 4-18, applicant argues that Robbins et al. discloses a method of screening for early detection of colorectal cancer, while the instant method is drawn to screening for recurrence of cancer, and thus that Robbins et al. has no teaching or disclosure of screening for recurrence of a cancer after removal of a primary tumor. Applicant's arguments filed 10-02-2001 have been fully considered but they are not persuasive.

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Applicant's arguments are not commensurate in scope with the claims. With regard to claims 1 and 4-18, the claims are drawn to "a method for estimating survival expectancy of a cancer patient", and not to a method of screening for recurrence of cancer. Further, Robbins et al. does disclose monitoring for recurrence of cancer after treatment (see column 3, lines 10-30).

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The rejection of pending claims 1-18, 47, 49-52, and 54-62 under 35 U.S.C. 103(a) as being unpatentable over Johansen et al, in view of Maggio et al., US Patent 4,828,981, issued 5/9/1989, or Harlow et al., Antibodies, A Laboratory Manual, Cold Spring Harbor Laboratory, 1988, pages 148-212, or Price et al., WO 95/01995, 1/19/1995 is maintained for reasons of record, and is applied to newly amended claims 38-39.

Applicant argues that the combination of references fails to teach YKL-40 as a prognostic marker for any cancer other than breast cancer, because the reference only exemplified prognosis of a single type of cancer. Applicant's arguments filed 10-02-2001 have been fully considered but they are not persuasive.

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As set forth in the previous office action, one of skill in the art, based on the teachings of Johansen et al., would have been motivated to substitute other cancers for breast cancer with a reasonable expectation of success, because Johansen et al. Exemplifies that YKL-40 is diagnostic for breast cancer. Further, Johansen et al. discloses that YKL-40 is overexpressed in pathologies which involve tissue remodeling, which would include all cancers. Further, Johansen et al. teaches that YKL-40 appears to be a glycosidase, which has activity which contributes to metastasis. This is a generalized mechanism of action which would apply to all cancers. Further, Johansen specifically states that it is likely that YKL-40 will be useful for monitoring other cancers. (See especially pages 1441-1442) Thus Johansen et al. provides more than a “suggestion to try”, but rather meets the legal standard under 35 U.S.C. 103(a) of a “reasonable expectation of success”.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set

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forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

December 30, 2001

